

REMARKS

Applicant thanks Examiner Sutton for his time and consideration of the above identified application during the telephonic interview of January 19, 2011 with the undersigned.

During the interview the results demonstrated in Table 3 of the present specification were compared to the cited references. Clarification of the ratings and the agglomerate properties in the table were requested. Also, possible amendments to the claims were discussed.

This application is amended in a manner to place it in condition for allowance at the time, and a Declaration under 37 CFR 1.132 by one of the named inventors, Philippe Lefevre, is provided in the appendix. The declaration discusses the ratings in Table 3, as well as the agglomerate properties, as requested during the interview.

Status of the Claims

Claim 19 now recites "pea starch".

Claims 19-22 and 24-47 remain pending.

Claim Rejections-35 USC §103

Claims 19-22, 24-27, 29, 30, 32-36 and 40-43 were rejected under U.S.C. § 103(a) as being unpatentable over LYDZINSKI et al. U.S. 2003/0099692 (LYDZINSKI) in view of

MCCREADY et al. Anal. Chem., 1950 (MCCREADY). This rejection is respectfully traversed for the reasons that follow.

The position of the Official Action was:

"At the time of the invention, it would have been obvious to modify the composition of Lydzinski et al. to include the smooth pea starch of McCready et al. since Lydzinski et al. teaches the use of legumes such as peas. It would have been within the purview of the skilled artisan to use any source of peas and to evaluate its usefulness in the invention based on the broad disclosure of "sources of starches are legumes such as peas" of Lydzinski et al. It would have also been obvious to use a hydroxypropylated smooth pea starch since Lydzinski et al. teaches hydroxypropylated legume starches."

However, as there is no reasoning provided for specifically selecting smooth pea starch from the starches of MCCREADY, the conclusion does not support the finding of obviousness.

"[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

LYDZINSKI fails to suggest that a 30-45% amylose content is preferred or even that pea starch is a preferred type of starch. To the contrary, LYDZINSKI very broadly describes a composition comprising a starch from a source such as "cereals, tubers, roots, legumes and fruits", wherein a native starch source is described as follows:

"The native source can be corn, pea, potato, sweet potato, banana, barley, wheat, rice, sago, amaranth, tapioca, arrowroot, canna, sorghum, and waxy or high amylose varieties thereof. As used herein, the term "waxy" is intended to include a starch containing at least about 95% by weight amylopectin and the term "high amylose" is intended to include a starch containing at least about 40% by weight amylose."

These starches may be subjected to any physical, chemical, and/or enzymatic modifications (see [0011] to [0013]), including hydroxypropylation. The examples of LYDZINSKI are limited to modified high amylose, i.e., 70%, or waxy corn starches, i.e., with no more than 5% amylose, and native tapioca starch (See [0039]-[0045]).

Thus, LYDZINKSI fails to provide guidance for selecting any starch having an amylose content of 30 to 45% amylose content.

MCCREADY was cited for teaching that smooth pea starch includes the claimed amylose content. However, MCCREADY provides a list of pea starch types. MCCREADY fails to indicate any preference for smooth pea starch, which has the claimed amylose content. Indeed, the majority of the pea starches listed by MCCREADY have an amylose content greater than the claimed amount.

Moreover, even if one would have randomly selected smooth pea starch from MCCREADY, there would have been no expectation of the superior results of the claimed invention, as demonstrated in Table 3 of the present specification. MCCREADY mentions nothing of film properties, and LYDZINSKI, as evidenced

by the examples, failed to recognize the superior film properties achieved by a pea starch with an amylose content of 30-45%.

As shown in Table 3, prepared starch compositions were rated for their film/coating properties on a scale (see page 18, line 12 of the specification) from "+++"(best) to "0"(worst). These ratings, and the agglomeration property, are explained in the Declaration provided in the Appendix.

Contrary to the remarks made in the Official Action, Table 3 does include starches taught by LYDZINSKI, albeit not explicitly.

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In Table 3, for example, there is waxy starch, high amylose starch and modifications that include hydroxypropylation. LYDZINSKI broadly describes these types of starches and hydroxypropylation.

Further contrary to the statements in the Official Action, Table 3 does make comparisons to establish unexpected results.

To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of

the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960).

In Table 3, the comparative starches include amylose contents greater and less than that claimed, as well as different modifications of the starch. The amylose contents greater than the claimed range and the different types of modification are disclosed by LYDZINSKI.

Thus, the results demonstrated by the claimed composition having amylose content of between 30 and 45% by dry weight of starch present in a composition and at least one hydroxypropylated pea starch, are unexpectedly superior in view of LYDZINSKI and MCCREADY.

Therefore, as the proposed combination fails to suggest the claimed invention or the unexpected results, the claims are not rendered obvious. Withdrawal of the rejection is respectfully requested.

Claims 31 and 44-46 were rejected under U.S.C. § 103(a) as being unpatentable over LYDZINSKI in view of MCCREADY, and further in view of FUERTES US 6,469,161 (FUERTES). This rejection is respectfully traversed for the reasons that follow.

For the reasons discussed above, LYDZINSKI and MCCREADY fail to render obvious a composition having amylose content of between 30 and 45% by dry weight of starch present in a composition and at least one pea starch.

FUERTES relates to a chemical fluidification process for a starchy material. However, FUERTES is completely silent about specific film-forming compositions, in particular composition comprising hydroxypropylated or acetylated legume starch and having a certain amylose content.

Consequently, FUERTES does not remedy the shortcomings of LYDZINSKI and MCCREADY for reference purposes.

Therefore, the claimed invention is not rendered obvious by the combination of LYDZINSKI MCREADY and FUERTES, and withdrawal of the rejection is respectfully requested.

Claims 19, 28, 37-39 and 47 were rejected under U.S.C. § 103(a) as being unpatentable over HAASMAA US 2002 0032254 (HAASMAA) in view of LEUSNER US 4,431,800 (LEUSNER) and further in view of KIM US 6,123,963 (KIM). This rejection is respectfully traversed for the reasons that follow.

The position of the Official Action was:

"At the time of the invention, it would have been obvious to modify the composition of Haasmaa et al. to include the smooth pea starch of McCready et al. since Haasmaa et al. teaches the use of native starches such as pea starch. It would have been within the purview of the skilled artisan to use any source of peas and to evaluate its usefulness in the invention based on the broad disclosure of "native starches such as pea starch" of Haasmaa et al.

At the time of the invention, it would have been obvious to modify the smooth pea starch suggested by combining Haasmaa et al. and McCready et al. with the methods of Leusner et al. to produce a hydroxypropylated pea starch for use as the starch component since it is a stable starch ether. It would have been obvious to use the starch composition suggested by combining Haasmaa et al., McCready et al. and Leusner et al. in coating processes of Kim et al. since it teaches that conventional methods of coating capsules include fluidized bed and dip-coating."

However, as there is no reasoning provided for specifically selecting smooth pea starch from the starches of MCCREADY, the conclusion does not support the finding of obviousness.

"[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

HAASMAA fails to provide any guidance for the selection of a starch with a amylose content from 30% to 45%. Instead, HAASMAA provides an exhaustive list of starch sources which includes barley, potato, wheat, oat, pea, corn, tapioca, sago, rice, or a similar rubber-bearing or rain plant, and HAASMA discloses that there may be anywhere from 0% to 100% amylose content ([0026]). Indeed, barley starches, or at least cereal starches, appear to be preferred as the Examples only utilize barley starches. Thus, HAASMAA provides no guidance in specifically choosing an amylose content of 30-45%.

MCCREADY was cited for teaching that smooth pea starch includes the claimed amylose content. However, MCCREADY simply provides a list of pea starch types. MCCREADY fails to indicate any preference for smooth pea starch, which has the claimed

amylose content. Indeed, the majority of the pea starches listed by MCCREADY have an amylose content greater than the claimed amount.

Neither LEUSNER nor KIM provides any guidance for selecting a starch with an amylose content of 30-45%. LEUSNER was cited for teaching the hydroxypropylation of starch, but LEUSNER notes that hydroxypropylation decreases the tendency towards retrogradation of the starches (column 1, lines 23-24). KIM was offered for teaching conventional methods for coating tablets, granules, pellets, crystals, and capsules include coating in a fluidized bed and dip-coating (column 6, lines 58-65).

Thus, the proposed combination of documents offers no suggestion or motivation for selecting a starch with an amylose content of 30-45%.

Moreover, if one would have randomly selected smooth pea starch from MCCREADY, there would have been no expectation of the superior results of the claimed invention, as demonstrated in Table 3 of the present specification. MCCREADY mentions nothing of film properties, and HAASMAA, as evidenced by the barley or cereal-based, examples, failed to recognize the superior film properties achieved by a pea starch with an amylose content of 30-45%.

As shown in Table 3, prepared starch compositions were rated for their film/coating properties on a scale (see page 18, line 12 of the specification) from “+++”(best) to “0”(worst).

These ratings, and the agglomeration property, are explained in the Declaration provided in the Appendix.

Contrary to the remarks made in the Official Action, Table 3 includes starches covered by the very broad disclosure of HAASMAA. However, no explicit comparison is noted.

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In Table 3, the comparative examples include starches with high and low amylose content, which would be included in the great number of starch sources from 0% to 100 amylose content disclosed by HAASMAA.

Further contrary to the statements in the Official Action, Table 3 does make comparisons to establish unexpected results.

To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960).

Table 3 compares starches with amylose contents either greater or less than the claimed invention, the entire range of which is broadly disclosed by HAASMAA.

Thus, the results demonstrated by the claimed composition having amylose content of between 30 and 45% by dry weight of starch present in a composition and at least one hydroxypropylated pea starch, are unexpectedly superior in view of HAASMAA, MCCREADY, LUESNER and KIM.

Therefore, as the proposed combination fails to suggest the claimed invention or the unexpected results, the claims are not rendered obvious. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims, the newly cited declaration and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or

credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- 37 CFR 1.132 Declaration of Philippe Lefevre